

AMENDMENTS TO THE CLAIMS:

1. (Currently Amended) A method for tracking samples of a clinical study,
comprising:

defining a first clinical study protocol comprising a plurality of procedures, wherein said
procedures comprise steps of laboratory procedures to be performed on at least some samples
5 comprising biological material;

accessioning said samples for said first clinical study protocol by recording in a computer
implemented database identifying information for said samples and identification of said first
clinical study;

creating a first worklist by assigning a ~~particular~~ first scientist to perform at least a
10 ~~particular~~ first procedure on ~~particular~~ a first set of samples recorded in said database;

creating a first checklist comprising steps of at least [[one]]a first procedure to be
performed on the samples of [[a]]said first worklist;

displaying said first checklist to said first scientist, wherein said first scientist performs
performing said steps of said first checklist; [[and]]

15 recording in said database a completion status and results of at least a portion of said
steps on said first checklist~~[[.]]~~;

initiating a query of said database for a status associated with at least a first of said
accessioned samples; and

generating a report in response to said query, said report including at least some of said
20 completion status or results stored in said database, wherein a status of said at least a first of said
accessioned samples is tracked.

2. (Original) The method of Claim 1, further comprising conducting the steps of said
method with regard to a second clinical study protocol, wherein said step of accessioning
samples includes associating at least a first sample with said first clinical study protocol and at
least a second sample with said second clinical study protocol, and wherein at least one worklist
5 assigned to a particular scientist comprises at least one sample associated with said first clinical
study protocol and at least a second sample associated with said second clinical study protocol.

3. (Original) The method of Claim 1, wherein said step of indicating completion and
results of at least a portion of said steps on said checklist comprises indicating completion of at
least one step for all samples on a checklist by one entry of information.

4. (Original) The method of Claim 1, wherein at least one of said procedures
determines the genotype of an individual.

5. (Original) The method of Claim 1, further comprising formalization of said
results by an activity selected from the group consisting of: inspection of results; inspection of

chain of custody records; entry of new results; inspection of procedures run; and modification and rejection of erroneous results.

6. (Currently Amended) A computer implemented method for tracking samples of a clinical study, comprising the steps of:

providing a computer having an associated memory;

providing a list of standard operating procedures, wherein each of said standard operating

5 procedures comprise procedure steps of laboratory procedures to be performed on at least some samples of biological material;

providing a list of samples of biological material; [[and]]

merging said list of standard operating procedures with said list of samples to generate a check list for use in connection with said clinical study, wherein said list of standard operating

10 ~~procedure~~procedures, said list of samples and said checklist are all stored in said computer

memory[[.]]; and

displaying a report including a status of said list of samples.

7. (Original) The method of Claim 6, wherein at least one of said procedures determines the genotype of an individual.

8. (Currently Amended) A computer implemented method for tracking samples of a clinical study, comprising:

providing a computer;

accessioning a plurality of biological samples, wherein identifying information is stored

5 in said computer;

determining procedures to be taken with respect to said biological samples, wherein said procedures comprise a plurality of steps;

defining at least a first workgroup comprising at least a first of said plurality of biological samples, wherein said first workgroup comprises at least one procedure to be performed on said

10 at least a first of said plurality of biological samples, and wherein said workgroup is stored in said computer;

preparing at least one checklist comprising said at least a first workgroup and said steps comprising said at least one procedure, wherein said checklist is stored in said computer;

displaying said checklist;

15 performing said steps; and

recording performance of said steps in said computer as said steps are performed.

9. (Original) The method of Claim 8, wherein at least one of said procedures determines the genotype of an individual.

10. (New) The method of Claim 1, wherein said status associated with at least a first of said accessioned samples includes at least one of: procedures performed with respect to a

sample, condition of a sample, results of procedures performed with respect to a sample, and a location of a sample.

11. (New) The method of Claim 1, wherein said report includes at least one of: genotype results, DNA integrity information, purification results, sample lists, audit trail information and an identification of a selected subset of said samples.

12. (New) The method of Claim 1, further comprising:
creating a second worklist by assigning one of said first scientist and a second scientist to perform at least a second procedure on a second set of samples recorded in said database, wherein at least one of said samples included in said second set of samples is included in said first set of samples;

creating a second checklist comprising steps of at least a second procedure to be performed on the samples of said second worklist; and
displaying said second checklist to said one of said first scientist and said second scientist, wherein said one of said first scientist and said second scientist performs said steps of said second checklist.

13. (New) The method of Claim 1, wherein said at least a first procedure comprises identifying at least one of a gene and an allele contained in a sample included in said first set of samples.

14. (New) The method of Claim 1, wherein said at least a first procedure includes at least one of: movement of a sample from one vessel to another, addition of a reagent to a sample, dilution of a sample, DNA concentration adjustment of a sample, changing a temperature of a sample, separating a first constituent of a sample from a second constituent of that sample, and
- 5 mixing a sample.